

10/031652



מדינת ישראל  
STATE OF ISRAEL

REC'D 16 JUN 2000	
WIPO	PCT

IL00/00269

4

Ministry of Justice  
Patent Office

משרד המשפטים  
לשכת הפטנטים

This is to certify that  
annexed hereto is a true  
copy of the documents as  
originally deposited with  
the patent application  
of which particulars are  
specified on the first page  
of the annex.

זאת לתעודה כי  
רצופים בזה העתקים  
נכונים של המסמכים  
שהופקדו לכתחילה  
עם הבקשה לפטנט  
לפי הפרטים הרשומים  
בעמוד הראשון של  
הנספח.

## PRIORITY DOCUMENT

SUBMITTED OR TRANSMITTED IN  
COMPLIANCE WITH RULE 17.1(a) OR (b)

This 14-05-2000 היום

רשם הפטנטים

Commissioner of Patents

נתאשר  
Certified

129903	מספר: Number
11-05-1969	תאריך: Date
הוקדם/נדחה Ante/Post-dated	

אני, (שם המבקש, בענו ולגבי גוף מאוגד - מקום התאגדותו)  
(Name and address of applicant, and in case of body corporate-place of incorporation)

S.I.N.A.I. - MEDICAL TECHNOLOGIES LTD.

ס.י.נ.א.י. - טכנולוגיות רפואיות בע"מ

64, Hashahar Str., Raanana  
43565, Israel

רח' השחר 64, רעננה, ישראל 43565

( Inventor's names - on the next page)

שם המצאה הוא  
of an invention the title of which is

1'72

בעל אמצאה מכח  
Owner, by virtue of

התקן לאיחוי שברי צוואר הירך

(בעברית)  
(Hebrew)

# OSTEOSYNTHESIS DEVICE FOR HOLDING TOGETHER IN COMPRESSION THE PARTS OF A FRACTURED FEMUR NECK

(באנגלית)  
(English)

hereby apply for a patent to be granted to me in respect thereof.

מבקש בזאת כי ינתן לי עליה פטנט

• בקשת חלוקה • Application of Division		• בקשת פטנט מוסף • Application for Patent Addition		• דרישה דין קדימה • Priority Claim		
מבקשת פטנט from Application	לבקשה/לפטנט to Patent/Appl.	מספר/סימן Number/Mark	תאריך Date	מדינת האגוד Convention Country		
No. _____ dated _____	No. _____ dated _____					
• יסודי כל: כללי / בידור - רצוף בזה / עוד יוגש P.O.A.: general/individual-attached/to be filed later- הוגש בענקי..... filed in case .....						
הען למסירת פטנטים בישראל Address for Service in Israel 64, Hashahar Str., Raanana 43565, Israel						
חתימת המבקש Signature of Applicant S.I.N.A.I. - MEDICAL TECHNOLOGIES LTD. Edward SHIFRIN, Director טכנולוגיות רפואיות בע"מ ח.פ. 51-277162-7		היום..... שנת..... This of the year of				
		לשימוש הלשכה For Office Use				

התקן לאיחוי שברי צוואר הירך

**OSTEOSYNTHESIS DEVICE FOR HOLDING TOGETHER  
IN COMPRESSION THE PARTS OF A FRACTURED  
FEMUR NECK**

Inventors: Ahi-Izil	IZILOV
Gennady	NICKELSHPUR
Zeev	AHARONSON

# **OSTEOSYNTHESIS DEVICE FOR HOLDING TOGETHER IN COMPRESSION THE PARTS OF A FRACTURED FEMUR NECK**

## **FIELD AND BACKGROUND OF THE INVENTION**

The invention relates to medicine and in particular to devices applied for osteosynthesis at femur neck fractures.

The FIG.1 drawing illustrates terms used here to define the location of femur parts and kinds of femur neck fractures. This drawing shows femur 11 (Hip bone), femur head 12 (Capitulum), femur neck 13 (Collum), characteristic femur areas- Trochanter major 14, Trochanter minor 15, Undertrochanter area 16, so-called Cortical layer 17 and Diaphysis 18.

Femur neck fractures (FIG.1) are divided into medial fractures and lateral fractures. Medial fractures include subcapital fracture 21, transcervical fracture 23 and basal fracture 25. Lateral fractures include transtrochanter fracture 27 and intertrochanter fracture 29.

The problem of treating femur neck fractures is of great social importance, especially in geriatrics. This kind of injuries is most frequent with elderly people. The number of such injuries essentially increases towards the age of 70 and is often caused by a relatively light trauma, non-coordinated movements, sharp turns, walking, going upstairs, lifting and carrying heavy loads, as due to senile osteoporosis characteristic of elderly people the bones become more brittle and fragile. Unfortunately femur neck fractures, especially subcapital fractures, knit badly, so that for elderly people they often become a fatal disaster.

Only in USA medical statistics estimates 250 thousand femur neck fractures annually. 20% of victims die within a year. After a year' treatment 15-20% of patients are still in need of care, with 50% of them aftereffects are found. \$ 7 billions are annually spent in USA to provide medical care of patients with femur neck fractures (H.W. Wahner, 1987).

The vast majority of elderly people with femur neck fractures have age changes of different prominence and suffer from internal diseases. They have limited reserve and protective forces of the organism. Even after correct and timely osteosynthesis with elderly and old people nonunion of femur neck fractures and development of femur head necrosis occurs nearly in 30 % of patients (A.V.Kaplan, 1979).

Most of patients in this age group suffer from pronounced osteoporosis. Therefore stops are badly fixed in a porous bone. This often results in a second displacement and nonunion of bone fragments. In this age subcapital femur neck fractures occur most frequently, and fragments fixing at osteoporosis appears to be inadequately stable. Therefore recently at femur neck fractures with elderly people endoprosthesis is performed. Total replacement of the thigh joint in such patients is carried out very seldom because of its traumatability, hemophilia as well as of osteoporosis and essential operational risk. Endoprosthesis at femur neck fractures is performed more often though there is a great number of contraindications to its application. It would not be correct to apply it at all femur neck fractures in elderly patients.

Closed osteosynthesis by means of a special device to treat such fractures would be the best way for elderly people. Even in case of its

unfavorable outcome in distant future it may provide sufficient existence of the patient in the immediate future.

Numerous devices have been developed world over for closed osteosynthesis at femur neck fractures, such as Compression Richard screw system by "Richards Manufacturing Co. Inc.", Memphis, Tennessee, USA, see U.S. Pat. No. 4,095,591.

The compression screw system includes an extension is provided for being nonrotatably fixed to a lag screw that is to be anchored to the head of a femur or other bone in a manner so as to allow compression to be applied to a fracture. The extension extends outward of the bone when attached to the lag screw is anchored to the bone to allow a compression plate to be easily positioned thereof. The cross section of the extension is substantially the same as the cross section of the lag screw to allow the compression plate to be easily and quickly passed onto the lag screw from the extension once the compression plate has been positioned on the extension.

The drawbacks of Richards system, in our opinion, are as follows:

a) to mount this system it is necessary to make a great cut in the femur muscular tissues to position a compression plate; b) the bone tissue of the femur head is drilled out over the whole duct length whereby bone tissue (trabeculae) and endosteum are essentially destructed, the blood supply

which is already insufficient is affected; c) the design of the introduced rod and its inadequately effective thread do not provide a stable compression connection of bone parts. At best bone fragments simply come in contact without a stable mutual fixation. Micromobility of bone fragments is as well possible.

Hence a conclusion may be made that Richards system is inefficient for the treatment of femur neck fractures, especially of subcapital fractures which simply do not knit in most cases.

Since the publication of U.S. Pat. No. 4,095,591 and up to now numerous improvements of Richards system have been made in USA and other countries, see U.S. Pat. No. 4,236,512; 4,432,358; 4,791,918; 4,794,919; 4,964,403; 5,871,485 (1978-1999), Patent of Israel No. 54025 (1978).

However all the above mentioned devices have the drawbacks of Richards system- high traumatability of the femur bone and tissues and inadequate efficiency for the treatment of femur neck fractures, such as medial fractures. The application of these devices for the treatment of subcapital fractures is simply unsuitable.



There are also known devices developed by "Howmedica International Inc." (see U.S. Pat. No. 5, 176, 681), "Smith & Nephew Richards Inc." (U.S. Pat. No. 5, 167, 663 and EP 0441577), "Endocare AG" (U.S. Pat. No. 5, 713, 902). These devices comprise a rod introduced inside the shin bone and a screw attached to this rod to fix the femur neck. The devices are unwieldy, may cause traumas to the patient, and their efficacy is on the level of the Richard system device.

There is further known an "Osteosynthesis device" disclosed in U.S. Pat. No. 5,437,674. An osteosynthesis device including a screw whose tip is pyramidal or conical and whose body is provided, at a distal end thereof, with an outside thread, wherein the head of the screw has a plurality of foldable small wings integral with the body and wherein the screw has a device for folding the small wings. The device is useful particularly for fractures of the scaphoid, of the medial malleolus, Garden fractures 1 and 2 of the neck of the femur, pertrochanterian fractures of the femur, and generally, for fractures of small bones, and for putting in place hip or shoulder stops.

However this device is also inadequately efficient for the treatment of femur neck fractures, such as medial fractures. It cannot be used for the treatment of subcapital fractures.

Closest to the claimed invention is the "Osteosynthesis device for femur neck fractures", USSR Pat. No. 938969. The device comprises a rod with a buttress thread on one end and a hold-down nut on the other end of the rod having an internal thread. There are also provided tabs located in apertures formed in the rod on the side of the hold-down nut and a mechanism for operating the tabs. The mechanism includes a screw disposed in the inner tread of the rod and engaging the tabs.

However this device also has some drawbacks. It is not universal as its design does not allow for the differences in linear femur neck dimensions with different people, different cortical layer thickness in the undertrochanter femur area, does not provide mobility of the antimigration device, and its anchoring in the bone is not secure enough. Therefore such a device must be manufactured individually for each patient or in series differing in dimensions according to anthropological parameters of different patients.

An object of the present invention is to provide a universal and simple device for compression treatment of all kinds of femur neck fractures including medial fractures, such as subcapital fracture which could be

adapted to any anthropological parameters of different patients, easily positioned and, if necessary, easily removed.

Another object of the present invention is to reduce traumatization of a patient's bones and tissues, the time of operation for osteosynthesis at femur neck fractures.

The third object of the present invention is to increase the reliability of anchoring the device in the bone and provide reliable holding together in compression the parts of a fractured femur neck.

### SUMMARY OF THE INVENTION

According to the present invention there is proposed an osteosynthesis device for holding together in compression the parts of a fractured femur neck comprising: a) a screw formed as a step-shaped rod, b) a means to impart rotary motion to the screw, c) an antimigration device for anchoring the screw inside the bone, d) a hold-down nut, e) at least one extension sleeve, f) at least one additional nut.

The step-shaped rod has a longitudinal axis, a through axial hole, a proximal end with a buttress self-tapping thread and a butt shaped as a truncated cone. There is also a distal end with external thread and an internal axial cavity which is provided with internal thread on its distal end and is

associated with the external cylindrical surface of the rod via several longitudinal apertures evenly arranged on this surface and parallel to the generatrix of this surface. The outer diameter of the rod distal end matches the outer diameter of the buttress self-tapping thread on its proximal end.

There is a means to impart rotary motion to the screw, which is disposed on the distal end of the screw and is shaped as a lateral groove.

The antimigration device for anchoring the screw inside the bone is located in the internal axial cavity and comprises a collet chuck with release tabs disposed in the apertures. The collet chuck also has a threaded axial hole.

There is also a mechanism for reciprocal movement of the collet chuck inside the axial cavity and a mechanism for release tabs operation.

The osteosynthesis device includes a hold-down nut located on the rod distal end and movable along its external thread, the nut having a rounded proximal butt and means for registration with a special wrench on the distal butt of the nut.

There is at least one extension sleeve with a through axial hole, a means for connection with the rod distal end and with the external thread. At least one additional nut is located on the external thread of the extension

sleeve and has a rounded proximal butt and means on its distal butt to register with a special wrench.

The claimed osteosynthesis device has a proximal end provided with external buttress self-tapping thread of triangular or trapezoidal cross section, and a front and a rear spiral surface in direction of the rod proximal end. The thread inner diameter and outer diameter are related as 2 : 3. The front surface of the thread is inclined at angles from 30 to 35 degrees. The rear spiral surface of the thread is inclined at angles from 2 to 4 degrees.

The screw proximal end is provided with external buttress self-tapping thread the ends whereof comprise a screw tap, and in the middle of the threaded area and in the body of the screw proximal end there are slots to receive bone chips produced at setting the screw.

The mechanism for reciprocal movement of the collet chuck inside the axial cavity comprises a threaded axial stud reciprocable in the threaded axial hole of this collet chuck, the stud having a lateral slot on its distal end.

The mechanism for release tabs operation comprises a release screw having a conical proximal end and a distal end with a lateral slot. This release screw is placed in the internal thread of the axial cavity to reciprocate and engage with release tabs of the collet chuck.

The osteosynthesis device has at least one extension sleeve with a through axial hole and external thread serving also as a means for connection with the rod distal end by engaging the internal thread of its internal axial cavity, the sleeve being provided with a lateral slot on its free end.

The osteosynthesis device includes a screw formed as a step-shaped rod and an additional strap applied to hold together bone parts solely in lateral femur neck fractures and mounted on the femur outer surface close to the undertrochanter area of the shin bone, the strap being provided with means for its rigid connection with the screw distal end.

The osteosynthesis device additionally comprises a set of adjusting tools including: i) a first spiral drill for the bone; ii) a second spiral drill for the bone; iii) a third spiral drill; iv) a screw holder for femur neck osteosynthesis; v) a special wrench for adjusting the screw for femur neck osteosynthesis together with the antimigration device; vi) a special wrench for adjusting the hold-down and additional nut of the screw for femur neck osteosynthesis; vii) an all-purpose wrench for femur neck osteosynthesis.

The first spiral drill for the bone has a central axis and a through longitudinal axial hole to receive a needle, and an outer diameter no less

than the inner diameter of the buttress self-tapping thread of the screw and the cutting spiral length no less than the maximum femur neck length.

The second spiral drill for the bone has a central axis and a through longitudinal axial hole to receive a needle and an outer diameter greater than the inner diameter of the buttress self-tapping thread by drilling tolerance in bone material and the cutting spiral length no less than the maximum femur neck length.

The third spiral drill for the bone has an outer diameter greater than the outer diameter of the screw distal end, and the cutting spiral length no less than the length of the screw cylindrical surface.

The screw holder for femur neck osteosynthesis comprises a body with a handle on one end and an axial threaded hole on the other end, and the thread of the holder corresponds to the thread on the screw distal end.

There is a special wrench to adjust the screw for femur neck osteosynthesis together with the antimigration device. The wrench includes a body with a handle on one end and an axial threaded hole on the other end. The body external surface around the axial hole is provided by external thread, in the body walls in this area a through lateral slot is formed inside whereof a reciprocable spring-loaded strap is located. The strap ends extend

from the slot and are operatively connected with a special nut disposed on the body external thread and movable along this thread.

There is also a special wrench for adjusting the hold-down and additional nuts. It comprises a body with a handle on one end and an axial hole on the other end, means for registration with the distal butt of a corresponding hold-down or additional nut being provided on the body butt near the axial hole.

There is further an all-purpose wrench comprising a body with a detachable handle in the middle thereof. On one end of the body there is a means to impart rotary motion to the screw or extension sleeve. It includes a step-shaped splined pin with means for matching slots on the butts of this screw or extension sleeve. On the body other end there are provided an axial hole and means for matching with an additional element of the all-purpose wrench. The additional element has planes for matching the above-mentioned body end of the all-purpose wrench and is adapted to engage the lateral slots on the distal end of the threaded stud and release screw.



## BRIEF DESCRIPTION OF THE DRAWINGS

The description of the present invention is accompanied by drawings wherein:

FIG. 1 shows the location of the most frequent femur neck fractures.

FIG. 2 shows an embodiment of the claimed osteosynthesis device with an additional strap.

FIG. 3 shows an additional sleeve and an additional nut.

FIG. 4 shows the most preferable embodiment of the claimed osteosynthesis device (longitudinal section).

FIG. 5 shows a section of the buttress self-tapping thread.

FIG. 6 shows an additional sleeve embodiment.

FIG. 7 shows the first spiral drill.

FIG. 8 shows the second spiral drill.

FIG. 9 shows the third spiral drill.

FIG. 10, 11 show the screw holder.

FIG. 12 – 14 show a special wrench to adjust the screw together with the antimigration device.

FIG. 15, 16 show a special wrench to adjust the hold-down and additional nuts.

FIG. 17, 18 show an all-purpose wrench.

FIG. 19-22 show the sequence of a femur neck osteosynthesis using the claimed device.

#### DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

According to the present invention there is proposed an osteosynthesis device for holding together in compression the parts of a fractured femur neck. This device (see FIG.2) includes: a) a screw 100 formed as a step-shaped rod, b) a slot 102 to impart rotary motion to the screw, c) an antimigration device 104 for anchoring screw 100 inside the bone, d) a hold-down nut 106. Besides there are (see FIG. 3): e) at least one extension sleeve 108, and f) at least one additional nut 110.

In another embodiment the osteosynthesis device includes a screw 100 (see FIG. 2) and an additional strap 113 applied to hold together in compression bone parts solely in lateral femur neck fractures and mounted on the femur outer surface close to undertrochanter area 16 of the shin bone, strap 113 being rigidly connected with screw 100 distal end.

In the most preferable embodiment of the osteosynthesis device (see FIG. 4) step-shaped rod 112 has a longitudinal axis 114, a through axial hole 116, a proximal end 118 with a buttress self-tapping thread 120 and a butt

122 shaped as a truncated cone. There is also a distal end 124 with external thread 126 and an internal axial cavity 128 which is provided with internal thread 130 on its distal end 132 and is associated with external cylindrical surface 134 of rod 112 via several longitudinal apertures 136 evenly arranged on this surface 134 and parallel to the generatrix of this surface. The outer diameter of rod distal end 124 matches the outer diameter of buttress self-tapping thread 120 on its proximal end 118.

External buttress self-tapping thread 120 (see FIG. 4) has, on proximal end 118 of rod 112, ends 138 and 140 comprising a screw tap, and in the middle of the threaded area and in the body of rod 112 proximal end 118 there are grooves 142 to receive bone chips.

External buttress self-tapping thread 120 (see FIG. 5) of triangular or trapezoidal cross section has a front 158 and rear 160 spiral surface in direction of rod 112 proximal end 118. The thread inner diameter and outer diameter are related approximately as 2 : 3. Front spiral surface 158 of thread 120 has a tilt angle  $\alpha$  from 30 to 35 degrees. The rear spiral surface 160 of thread 120 has a tilt angle  $\beta$  from 2 to 4 degrees.

Antimigration device 150 for anchoring screw 100 inside the bone (see FIG. 4) is located in internal axial cavity 128 and comprises a collet

chuck 152 with release tabs 154 disposed in apertures 136. The collet chuck 152 also has a threaded axial hole 156 along its axis.

The osteosynthesis device also includes a hold-down nut 162 located on rod 112 distal end 124 and movable along its external thread 126, nut 162 having a rounded proximal butt 164 and recesses 166 for registration with a special wrench on the distal butt of the nut (see FIG. 6).

Extension sleeve 168 (see FIG. 6) has a step-shaped form, through axial hole 170, external thread 172 to engage distal end 124 of rod 112, and external thread 174 which is similar to external thread 126 of rod 112, sleeve 168 being provided with a lateral groove 169 on its free end. Extension sleeve 168 may have a different design (see FIG. 4) wherein outer thread 172 extends over the whole external surface of this sleeve 168. At least one additional nut 176 is located on outer thread 172 of extension sleeve 168 and has a rounded proximal butt 178 and recesses 180 on its distal butt to match a special wrench (see FIG. 4).

The osteosynthesis device (see FIG. 4) includes a mechanism for axial reciprocal movement of collet chuck 152 inside axial cavity 128 and a mechanism for release tabs 154 operation. The mechanism for axial reciprocal movement of collet chuck 152 inside axial cavity 128 is a

threaded axial stud 182 reciprocable in threaded axial hole 156 of collet chuck 152, stud 182 being provided with a lateral slot 184 on its distal end. The mechanism for release tabs 154 operation is a release screw 186 having a cone 188 on the proximal end and a lateral slot 190 on the distal end. This release screw 186 is positioned in internal thread 130 of internal axial cavity 128 to reciprocate and engage release tabs 154 of collet chuck 152.

The osteosynthesis device additionally comprises a set of adjusting tools including: i) a first spiral drill for the bone; ii) a second spiral drill for the bone; iii) a third spiral drill; iv) a screw holder for femur neck osteosynthesis; v) a special wrench for adjusting the screw for femur neck osteosynthesis together with the antimigration device; vi) a special wrench for adjusting the hold-down and additional nut of the screw for femur neck osteosynthesis; vii) an all-purpose wrench for femur neck osteosynthesis.

The first spiral drill 200 for the bone (see FIG. 7) has a central axis 202 and a through longitudinal axial hole 204 to receive a needle, and an outer diameter no less than the inner diameter of buttress self-tapping thread 120 of screw 100 and cutting spiral 206 length no less than the maximum femur neck length.

The second spiral drill 210 for the bone (see FIG. 8) has a central axis 212 and a through longitudinal axial hole 214 to receive a needle and an outer diameter greater than the inner diameter of buttress self-tapping thread 120 by drilling tolerance in bone material and cutting spiral 216 length no less than the maximum femur neck length.

The third spiral drill 220 for the bone (see FIG. 9) has an outer diameter greater than the outer diameter of screw 100 distal end, and cutting spiral 222 length no less than the length of rod 112 cylindrical surface 134.

Screw 100 holder 230 for femur neck osteosynthesis (see FIG. 10) comprises a body 232 with a handle 234 on one end and an axial threaded hole 236 on the other end and the thread of the holder corresponds to external thread 126 on screw 100 distal end 124. Body 232 of holder 230 has a through axial hole 238 (see FIG. 11).

There is a special wrench 240 to adjust screw 100 for femur neck osteosynthesis together with antimigration device 150 (see FIG. 12). Wrench 240 includes a body 242 with a handle 244 on one end and an axial threaded hole 246 on the other end. External surface 248 of body 242 around axial threaded hole 246 is provided with external thread 250 (see FIG. 13), in body 242 walls in this area a through lateral groove 252 is formed inside whereof a reciprocable spring-loaded strap 254 (see FIG. 14) is located.

Strap 254 ends extend from groove 252 and are operatively connected with a special nut 256 disposed on body 242 external thread 250 and movable along this thread 250. Strap 254 is loaded by pusher 258 with spring 260 (see FIG. 13, 14).

There is also a special wrench 280 for adjusting hold-down 162 and additional 176 nuts (see FIG. 15, 16). It comprises a body 282 with a handle 284 on one end and an axial hole 286 on the other end, pins 288 being provided on butt of body 282 near axial hole 286 for registration with recesses 166 or 180 on the distal butt of a corresponding hold-down 162 or additional 176 nut.

The set of adjusting tools further includes all-purpose wrench 300 comprising body 302 with a detachable handle 304 in the middle thereof. On one end of body 302 there is a means to impart rotary motion to screw 100 or extension sleeve 168. It includes a step-shaped splined pin 306 with splines 308 for matching lateral grooves 102 or 169 respectively on the butts of this screw 100 or extension sleeve 168. On the other end of body 302 there are provided an axial hole 310 and projections 312 for matching with an additional element 320. Additional element 320 has planes 322 for matching with projections 310 and a spline 324 adapted to engage lateral

groove 184 or 190 on the distal end of threaded stud 182 or release screw 186.

The claimed device is applied as follows.

Fracture fragments are reponed under periodic X-ray observation. A 3-4 cm long cut is made to expose undertrochanter area 16 of the femur bone. In the spot wherein Trochanter major changes to Diafiz 18 a twist drill needle is passed, by means of a drill, in direction of the femur neck axis. The bone cortical layer 17, 2 cm thick, is removed by a chisel around the needle end. Then, under periodic X-ray control, a hole is drilled out using in succession first spiral drill 200, second spiral drill 210 and third spiral drill 220 (see FIG. 19). In this case first spiral drill 200 and second spiral drill 210 are set by their longitudinal axial hole, 204 and 214 respectively, onto twist drill needle, and the drill is advanced in direction of the femur neck axis using the twist drill needle as a guide rod. The drilling depth is a little greater than the length of screw 100. Third spiral drill 220 is advanced by a brace to the depth of this part of the hole which exceeds a little the length of cylindrical external surface 134, drilling out the hole which remained after the passage of drills 200 and 210.



Then driving of screw 100 (see FIG. 20) is started. By this moment screw 100 is already set by its external thread 126 in axial threaded hole 236 of holder 230 and fixed in this holder 230 by hold-down nut 162. Screw 100 is passed through this part of the bone hole which has been drilled out by third drill 220, and then driven in the remaining part of this hole using end 138 of external buttress self-tapping thread 120 (see FIG. 20) as a screw tap. Bone chips generated in the process fill grooves 142 in the middle of the threaded portion and in the body of proximal end 118 of rod 112. At this stage it is possible to use a twist drill needle as a guide rod to set screw 100 more precisely. To this end the twist drill needle is passed in through axial hole 116 of screw 100 and in through axial hole 238 in body 232 of holder 230 (see FIG. 20). Once screw 100 has been driven, holder 230 is separated from screw 100, and inside axial cavity 128 of screw 100 there is mounted antimigration device 150. Such a procedure of setting screw 100 is used when the severity of bone osteoporosis is very high.

The most preferable variant is to set screw 100 together with antimigration device 150 (see FIG. 21). For this purpose a special wrench 240 is used. Screw 100 is previously inserted by its external thread 126 in axial threaded hole 246 of a special wrench 240 and fixed in this wrench 240 by hold-down nut 162. Therewith strap 254 is moved along groove 252

by a special nut 256, introduced into groove 102 on the distal end of screw 100 and fixed in this position in groove 102. Thereafter driving of screw 100 (see FIG. 21) is started by turning handle 244 of special wrench 240. This is carried out in the same way as by holder 230. Once screw 100 has been driven, special wrench 240 is separated therefrom. To facilitate unscrewing a special nut 256 is slightly turned in direction of the proximal end of screw 100, strap 254 being slightly advanced along groove 252 and acting axially on groove 102 of screw 100.

Once screw 100 has been mounted, femur head 12 and neck 13 are made coincident and held down in compression. To this end special wrench 280 is put over hold-down nut 162, by matching pins 288 of wrench 280 with recesses 166 on butt of hold-down nut 162. Then, by turning special wrench 280, nut 162 is held down until it is against the bone cortical surface 17. The tightening of nut 162 by means of buttress thread 120 causes compression of the bone endosteum. The femur head 12 and neck 13 are made coincident and pressed together tightly.

If the length of screw 100 is inadequate, it can be increased by using one or several extension sleeves 168 (see FIG. 6). Sleeve 168 is partly screwed in along thread 130 into internal axial cavity 128 of screw 100 by means of all-purpose wrench 300. In this case, to hold together femur head

12 and neck 13, instead of hold-down nut 162, additional nut 176 is used. Nut 176 is screwed up by means of the same special wrench 280.

On making the bone parts coincident in compression, antimigration device 150 (see FIG. 22) is positioned in the desired place and fixed. To position antimigration device 150 in the desired place threaded axial stud 182 is turned by means of additional element 320 of all-purpose wrench 300. Therewith collet chuck 152 of antimigration device 150 advances along internal axial cavity 128 (under periodic X-ray control) until the ends of its release tabs 154 come into the necessary position inside the bone, near cortical layer 17. Then release tabs 154 are drawn aside and extended from apertures 136 by means of release screw 186 moved along thread 130 by means of additional element 320 of all-purpose wrench 300. Thereby antimigration device 150 is fixed in the desired position and a paddle system is formed to hold screw 100 inside the bone and exclude mobility and rotation of bone fragments.

**Solely in treating lateral fractures of femur neck** it is possible to apply strap 113, which is placed on the femur external surface near undertrochanter area 16 (see FIG. 2). In this case strap 113 is rigidly connected with the distal end of screw 100.

If necessary, screw 100 may be removed after the union of femur neck parts. For this purpose the above procedure is carried out in the reverse order. First release screw 186 is removed, then, by turning axial threaded stud 182, collet chuck 152 of antimigration device 150 is moved inside axial cavity 128, opening thereby its release tabs 154 and retracting them into apertures 136. This is carried out by means of additional element 320 of all-purpose wrench 300. Thereafter, by means of special wrench 280, hold-down nut 162 is unscrewed (and strap 113 is removed if it has been mounted). Then special wrench 240 or holder 230 is screwed on thread 126 and fixed in this position. Thereupon screw 100 is removed from the femur neck. To facilitate the removal of screw 100, end 140 of its self-tapping buttress thread 120 is formed as a screw tap. Such a design of thread 120 allows to use its end 140 for cutting off excrescences of bone tissue which have grown in the hole channel in the femur neck wherefrom screw 100 is removed. The removal of screw 100 is performed under periodic X-ray control.

Application of the claimed device for femur neck osteosynthesis provides accurate and secure matching of bone fragments in compression during the whole period of the fracture union. Besides the duration of

surgical interference is essentially reduced and traumatization of endosteum and bone marrow of the femur head and neck is insignificant. The claimed device is suitable for compression treatment of all kinds of femur neck fractures, including medial fractures, such as subcapital fracture. And finally the claimed device is adapted to any anthropological parameters of different patients, easily mounted and, when necessary, easily removed.

Obviously, numerous modifications and variations of the present invention are possible in light of the above teachings. It is therefore to be understood that within the scope of the appended claims, the invention may be practiced otherwise than as specifically described herein.

## CLAIMS

We claim:

1. An osteosynthesis device for holding together in compression the parts of a fractured femur neck comprising:
  - a) a screw designed as a step-shaped rod having a through axial hole, a proximal end with self-tapping thread and a butt shaped as a truncated cone, and a distal end with external thread and internal axial cavity which is provided with internal thread on the distal end and is associated with a cylindrical external surface of said rod via several longitudinal apertures evenly arranged on this surface, parallel to the generatrix of said surface, the outer diameter of said rod distal end corresponding to the outer diameter of a buttress self-tapping thread on the proximal end of said rod;
  - b) a means to impart rotary motion to the screw disposed on the distal end of said screw;
  - c) an antimigration device for anchoring said screw inside the bone located in said internal axial cavity and comprising a collet chuck with release tabs disposed in said apertures, and a mechanism for

reciprocal movement of the collet chuck inside said axial cavity and a mechanism for release tabs operation;

- d) a hold-down nut located on said rod distal end and movable axially along its external thread, said nut having a rounded proximal butt and means for registration with a special wrench on the distal butt of the nut.
- e) at least one extension sleeve having a through axial hole, a means for connection with the rod distal end and an external thread;
- f) at least one additional nut located on the external thread of at least one said extension sleeve and having a rounded proximal butt and means on its distal butt to register with a special wrench.

2. A device according to claim 1, wherein said screw comprises a step-shaped rod, the proximal end whereof is provided with an external buttress self-tapping thread having spiral surfaces, front and rear in direction of said proximal rod end, the internal and external diameter of said thread are related approximately as 2 : 3.

3. A device according to claim 2 wherein said buttress self-tapping thread is of triangular cross section.

4. A device according to claim 2 wherein said buttress self-tapping thread is of trapezoidal cross section.
5. A device according to claim 2 wherein said front spiral surface of said thread is inclined at angles from 30 to 35 degrees.
6. A device according to claim 2 wherein said rear spiral surface of said thread is inclined at angles from 2 to 4 degrees.
7. A device according to claim 2 wherein the distal end of said screw is provided with an external buttress self-tapping thread the ends whereof are shaped as screw tap, and in the middle of the threaded portion and in the body of said screw proximal end there are grooves to receive bone chips produced during said screw positioning.
8. A device according to claim 1 wherein said means to impart rotary motion to the screw disposed on the distal end of said screw is a lateral groove.
9. A device according to claim 1 wherein said antimigration device is located in said internal axial cavity and formed as a collet chuck with



release tabs and a threaded axial hole, a mechanism of axial reciprocal movement of the collet chuck inside said axial cavity and a mechanism for release tabs operation.

10. A device according to claim 9 wherein said mechanism of axial reciprocal movement of said collet chuck inside said axial cavity is a threaded axial stud reciprocable in the threaded axial hole of said collet chuck, the stud being provided with a lateral slot on its distal end.
11. A device according to claim 9 wherein said mechanism of release tabs operation is a release screw having a conical proximal end and a distal end with a lateral slot, said release screw being positioned in the internal thread of said axial cavity to reciprocate and interact with said release tabs of said collet chuck.
12. A device according to claim 1 wherein at least one said extension sleeve has a through axial hole and external thread which also serves as said means for connection with said rod distal end by engaging the internal thread of said internal axial cavity, the sleeve having a lateral slot on its free end.

13. A device according to claim 1 including a screw formed as a step-shaped rod with said antimigration device, said hold-down nut, at least one said extension sleeve and at least one said additional nut, as well as an additional strap applied for holding together in compression bone parts at lateral fractures of the femur neck and mounted on the femur external surface near the undertrochanter area of the shin bone, said strap being provided with means for rigid connection with said screw distal end.

14. An osteosynthesis device for holding together in compression the parts of a fractured femur neck additionally comprising a set of adjusting tools including:

- i) a first spiral drill for the bone;
- ii) a second spiral drill for the bone;
- iii) a third spiral drill;
- iv) a screw holder for femur neck osteosynthesis;
- v) a special wrench to position said screw for femur neck osteosynthesis together with said antimigration device;
- vi) a special wrench to mount said hold-down nut and additional nut of said screw for femur neck osteosynthesis;
- vii) an all-purpose wrench for femur neck osteosynthesis.

15. A device according to claim 14 wherein said first spiral drill for the bone has a central axis and a through longitudinal axial hole to receive a needle and an outer diameter no less than the inner diameter of the buttress self-tapping thread of said screw and a cutting spiral length no less than the maximum length of the femur neck.
16. A device according to claim 14 wherein said second spiral drill for the bone has a central axis and a through longitudinal axial hole to receive a needle, as well as an outer diameter greater than the inner diameter of said self-tapping thread by drilling tolerance in bone material and a cutting spiral length no less than the maximum length of said femur neck.
17. A device according to claim 14 wherein said third spiral drill for the bone has an outer diameter greater than the outer diameter of said screw distal end, and a cutting spiral length no less than the length of said screw cylindrical surface.
18. A device according to claim 14 wherein said screw holder for femur neck osteosynthesis comprises a body with a handle on one end and an

axial threaded hole on the other end, the thread of said hole corresponding to said external thread on said screw distal end.

19. A device according to claim 14 wherein said special wrench to position said screw for femur neck osteosynthesis together with said antimigration device includes a body with a handle on one end and an axial threaded hole on the other end, the external surface of the body around said axial hole is provided with external thread, in said body walls in this area there is provided a through lateral groove inside whereof there is located a spring-loaded reciprocable strap the ends whereof extend from the groove and are operatively connected with a special nut located on said body external thread and movable along this thread.
20. A device according to claim 14 wherein said special wrench to position said hold-down nut and said additional nut of said screw for femur neck osteosynthesis comprises a body with a handle on one end and an axial hole on the other end, and on said body butt, near said axial hole, there are means for matching the distal butt of a corresponding hold-down or additional nut.

21. A device according to claim 14 wherein said all-purpose wrench for femur neck osteosynthesis comprises a body with a handle in the middle thereof, and on one end of said body there is said means to impart rotary motion to said screw or extension sleeve, said means comprising a step-shaped splined pin with means for matching lateral grooves on the distal butt of said screw or extension sleeve, and on the other end of said body there are provided an axial hole and means for matching an additional element.

22. A device according to claim 21 wherein said all-purpose wrench for femur neck osteosynthesis is provided with an additional element matching one of its ends and adapted to engage the lateral slots on said distal end of said threaded stud and release screw.

## ABSTRACT

The present invention relates to medicine, and more particularly, to devices applied for osteosynthesis at femur neck fractures. The device comprises a screw formed as a step-shaped rod having a longitudinal axis, a through axial hole, a proximal end with a buttress self-tapping thread and a butt shaped as a truncated cone, as well as a distal end with external thread and an internal axial cavity which is provided with internal thread on its distal end and associated with cylindrical external surface of the rod via several longitudinal apertures evenly arranged over this surface, parallel to the generatrix thereof, the outer diameter of the rod distal end corresponds to the outer diameter of the self-tapping thread on its proximal end. There is an antimigration device to fix the screw inside the bone located in the internal axial cavity and comprising a collet chuck with release tabs disposed in apertures, a mechanism for axial reciprocal movement of the collet chuck inside said axial cavity and a mechanism for release tabs operation. The device further includes a hold-down nut located on the rod distal end, at least one extension sleeve and at least one additional nut disposed on external

thread of said extension sleeve. The osteosynthesis device is additionally provided with a set of adjusting tools which includes drills for the bone, a screw holder and wrenches to adjust the screw, a hold-down and additional nut, as well as the antimigration device elements. The device may be provided with an additional strap for treatment of lateral femur neck fractures.

**22 Claims, 12 Drawing Sheets**

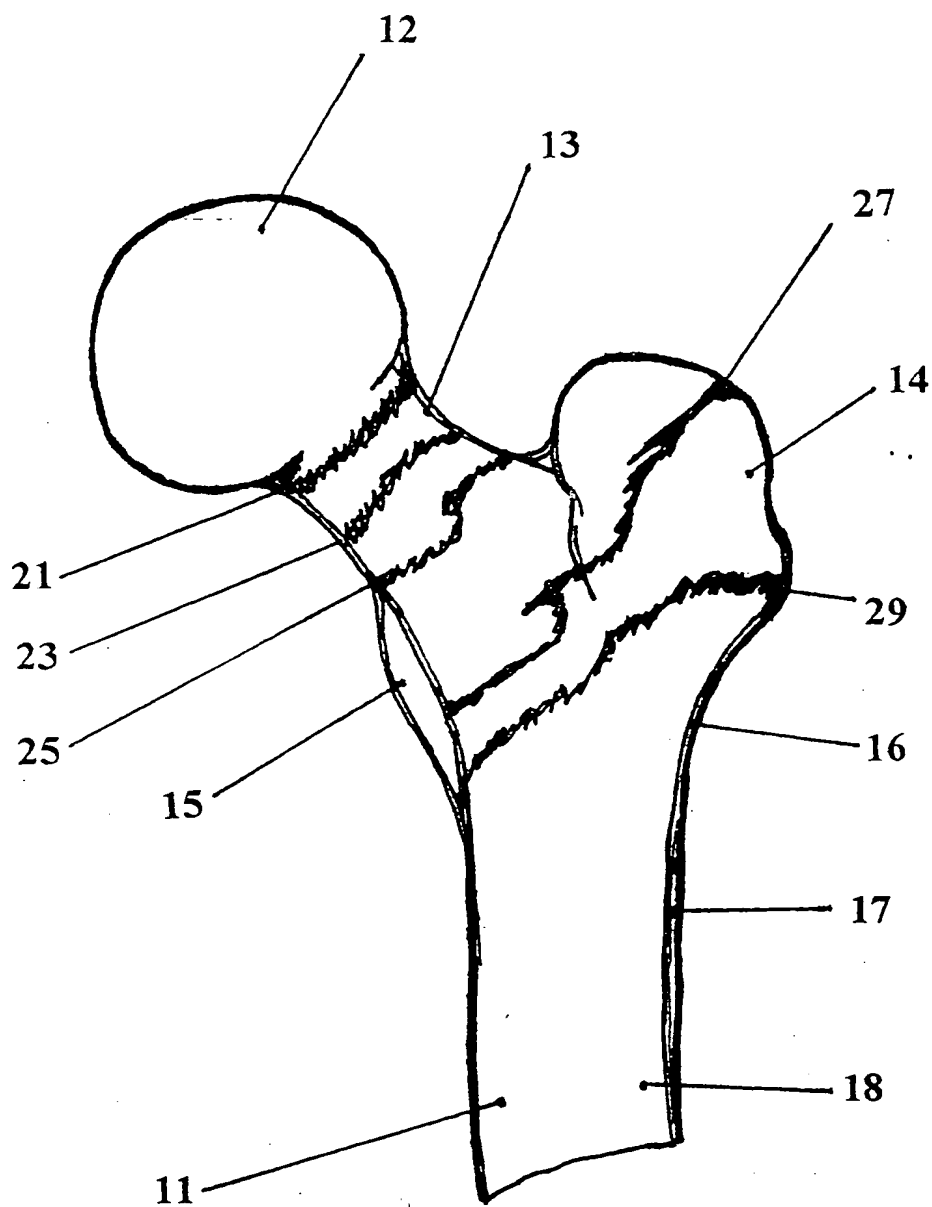
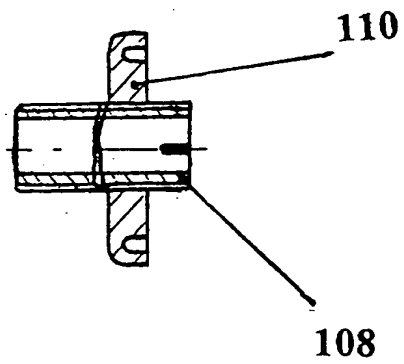
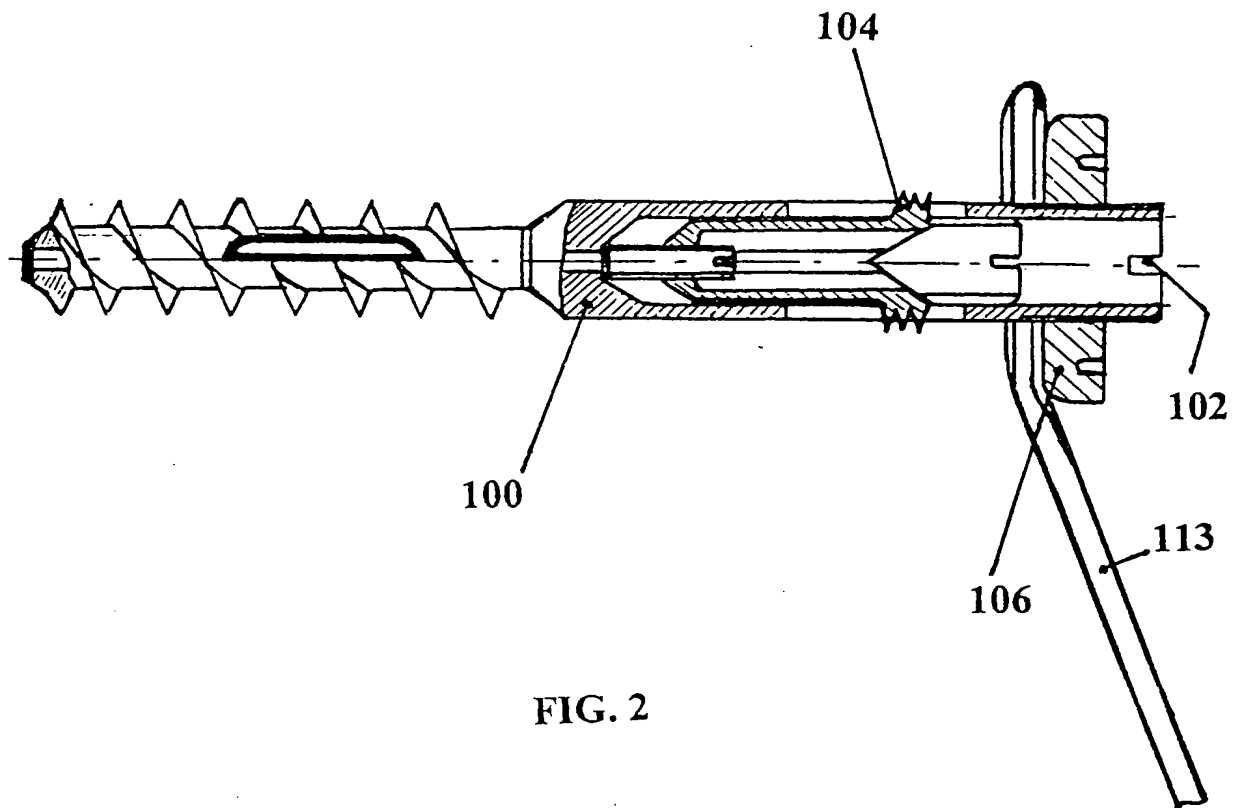


FIG. 1





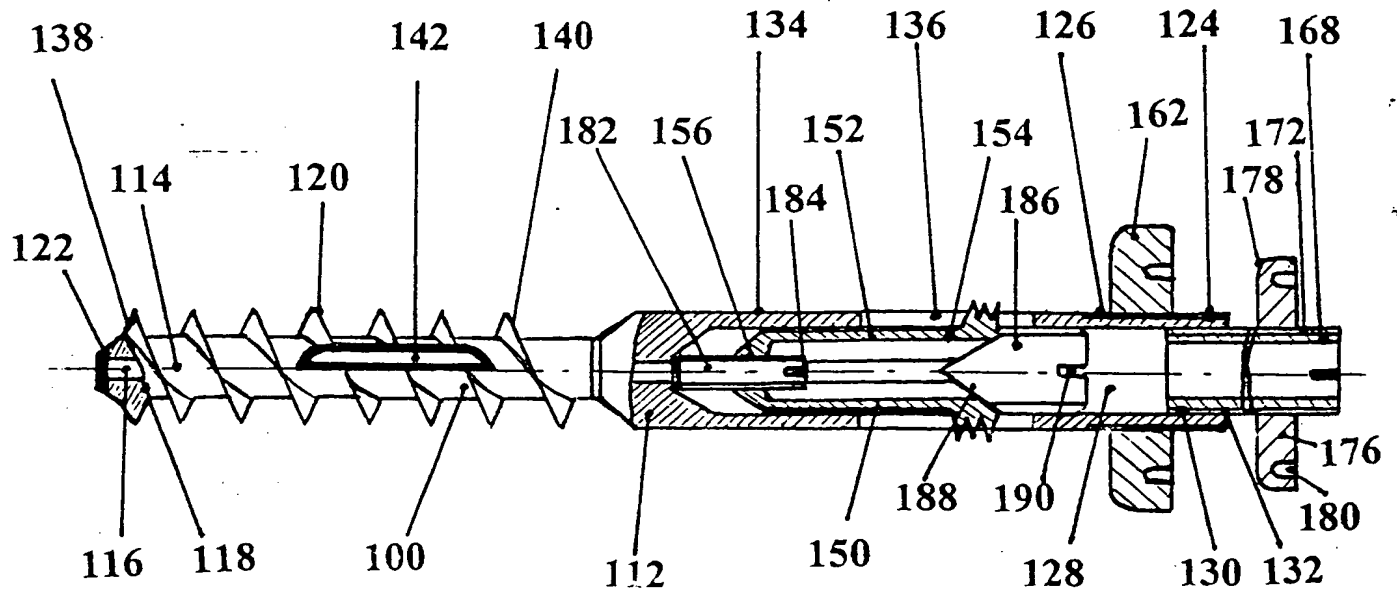


FIG. 4

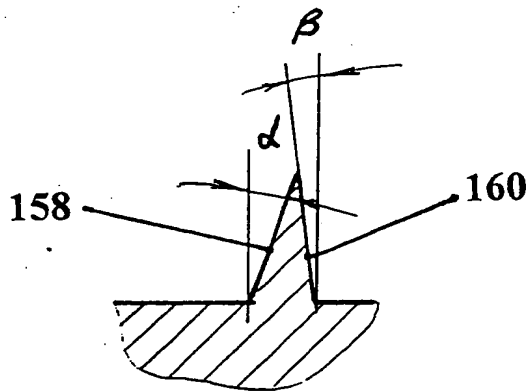


FIG. 5

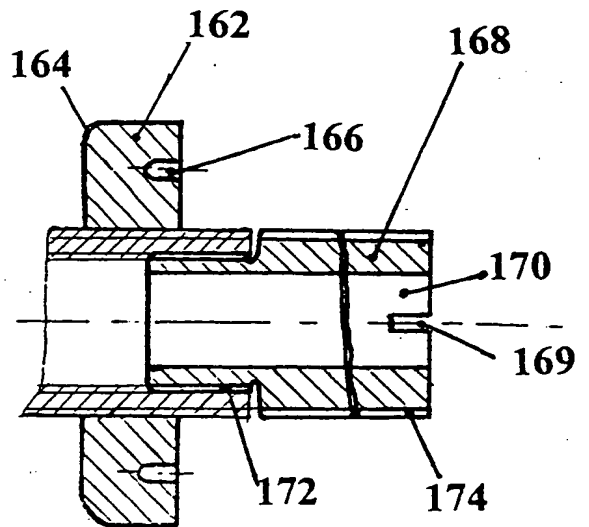


FIG. 6

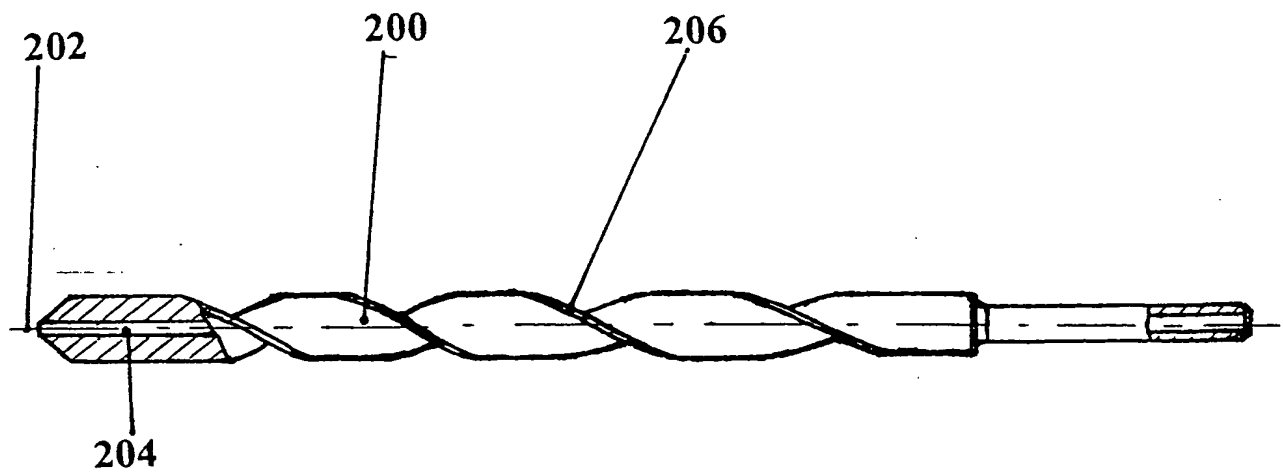


FIG. 7

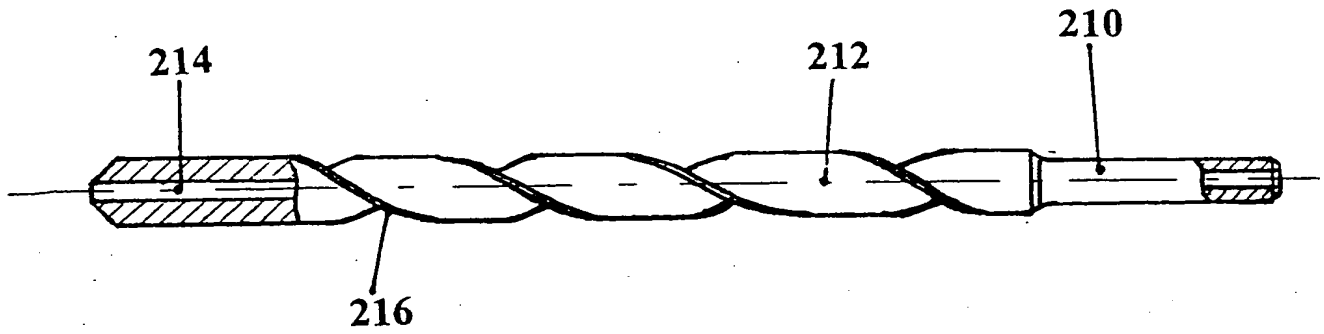


FIG. 8

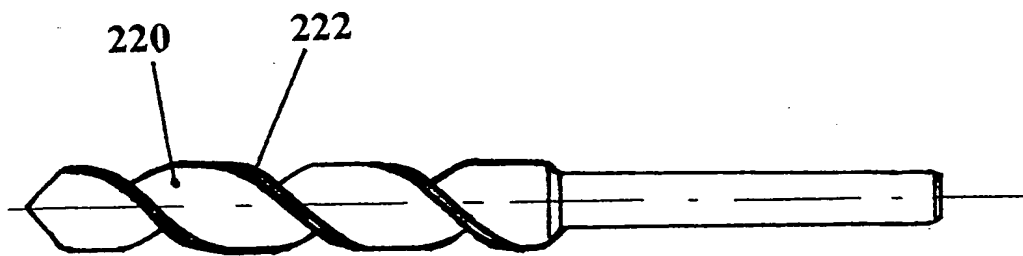


FIG. 9

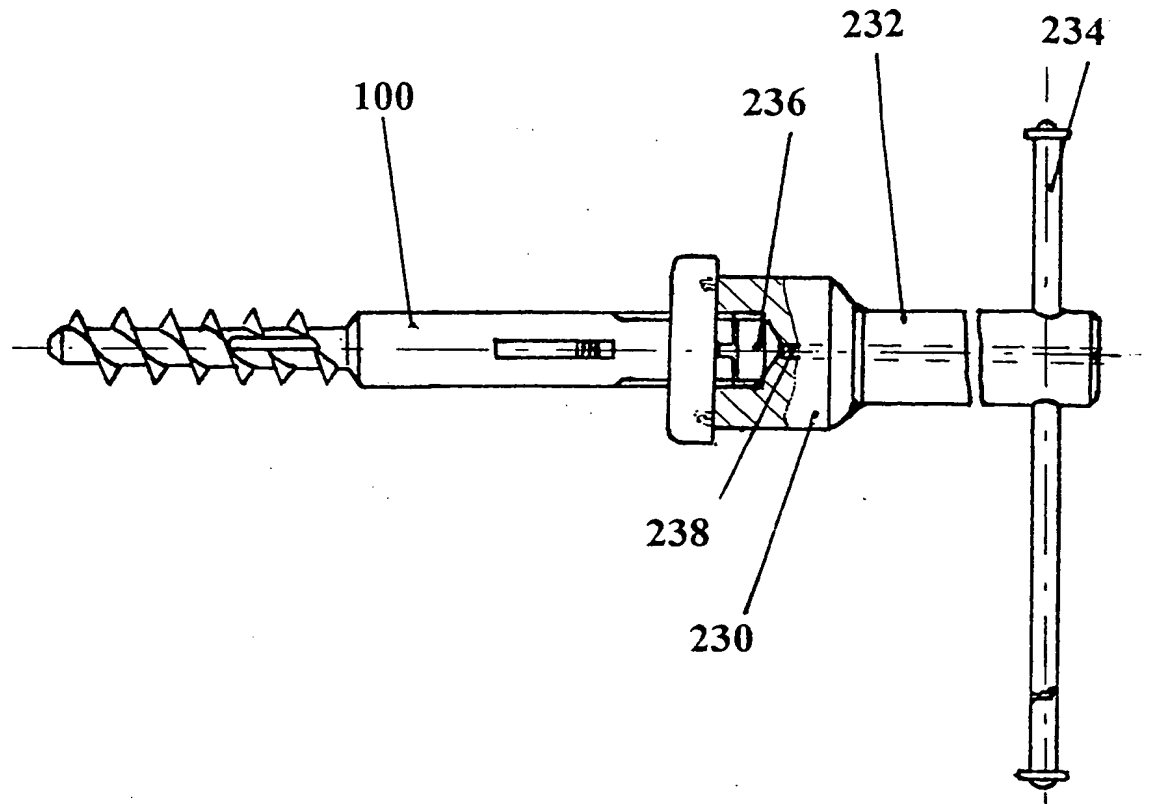


FIG. 10

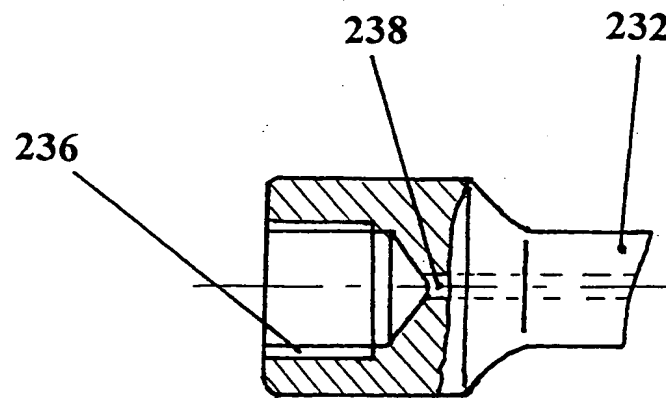


FIG. 11

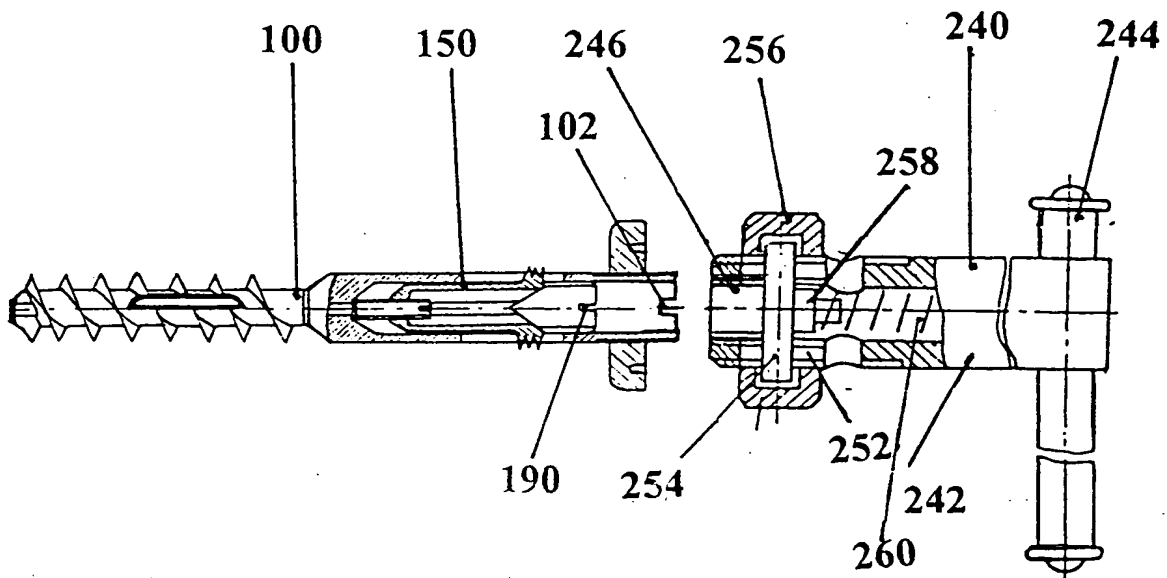


FIG. 12

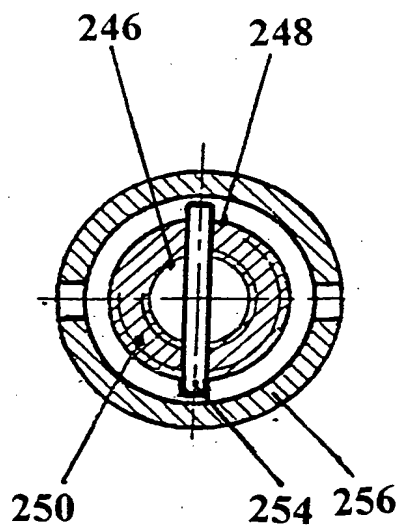


FIG. 13

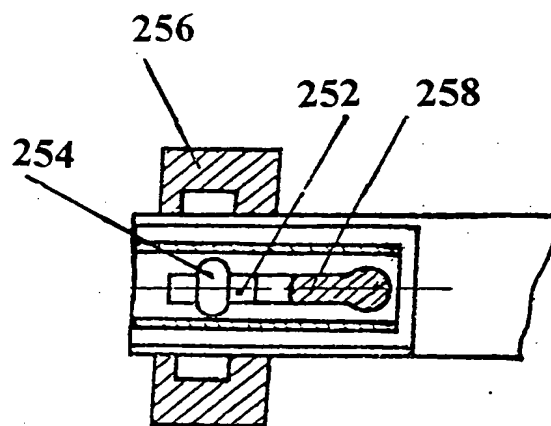


FIG. 14

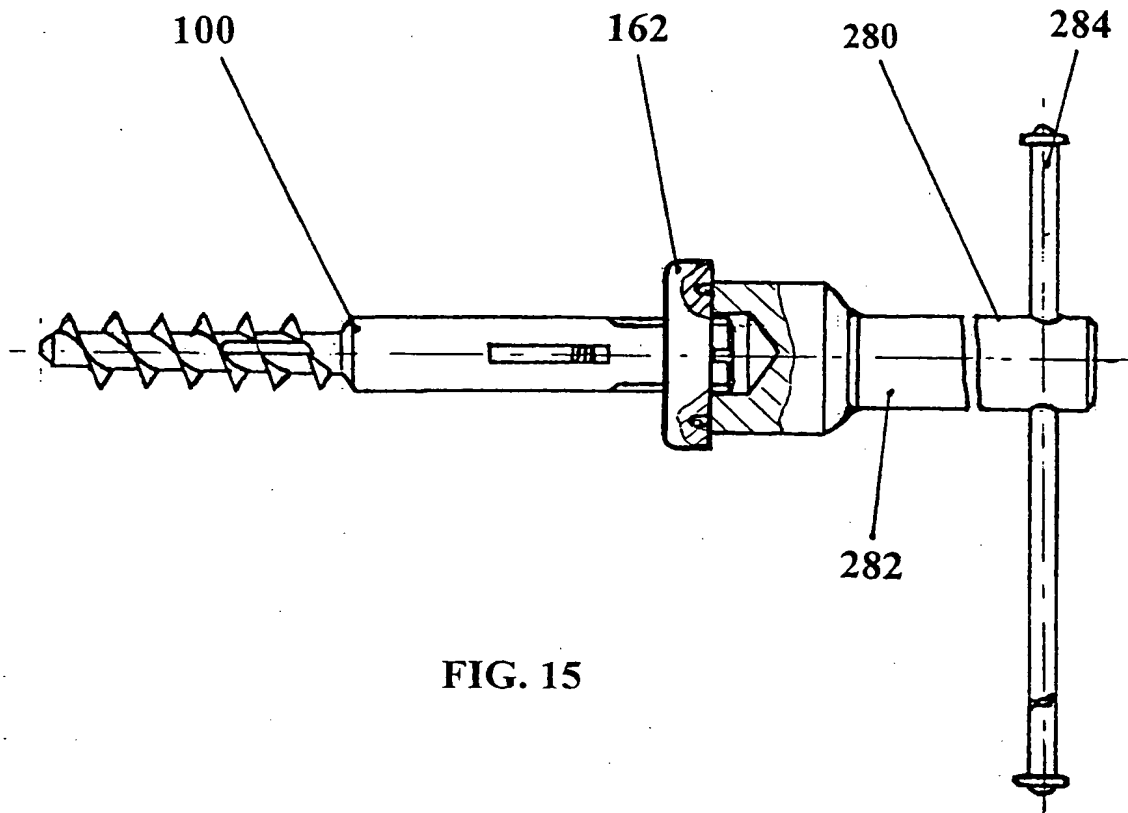


FIG. 15

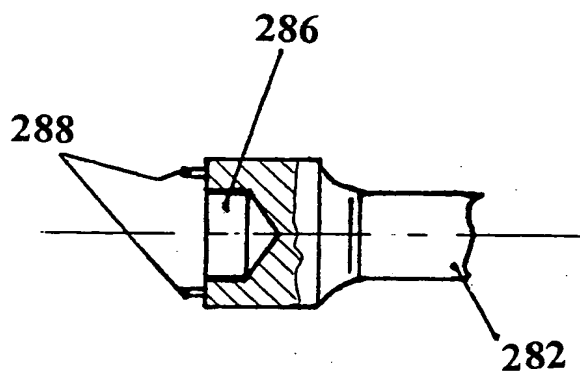


FIG. 16

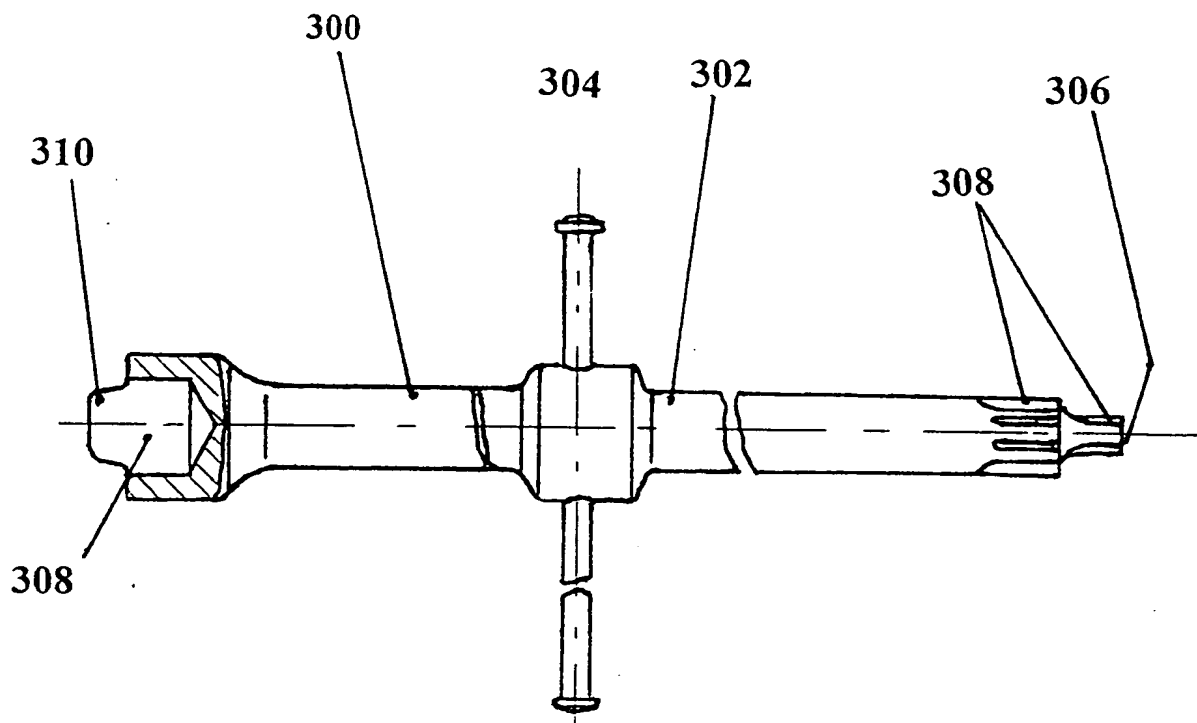


FIG. 17

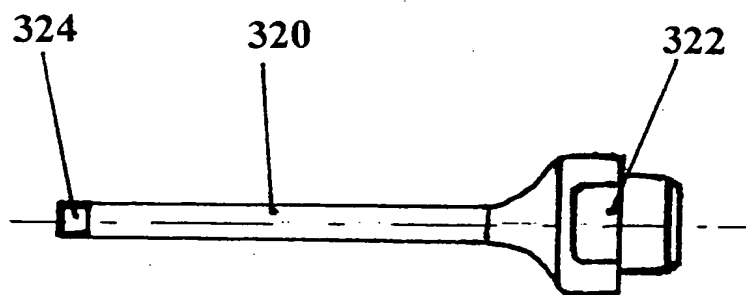


FIG. 18

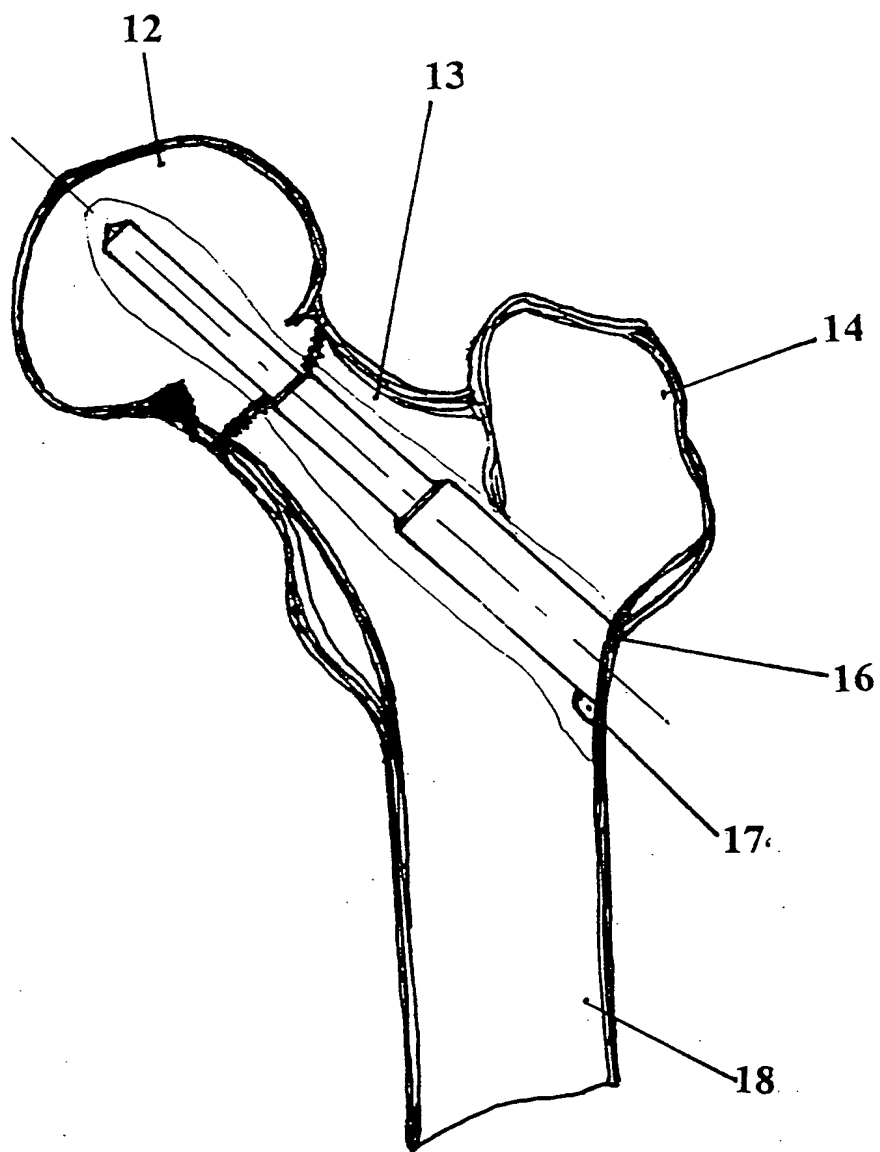


FIG. 19



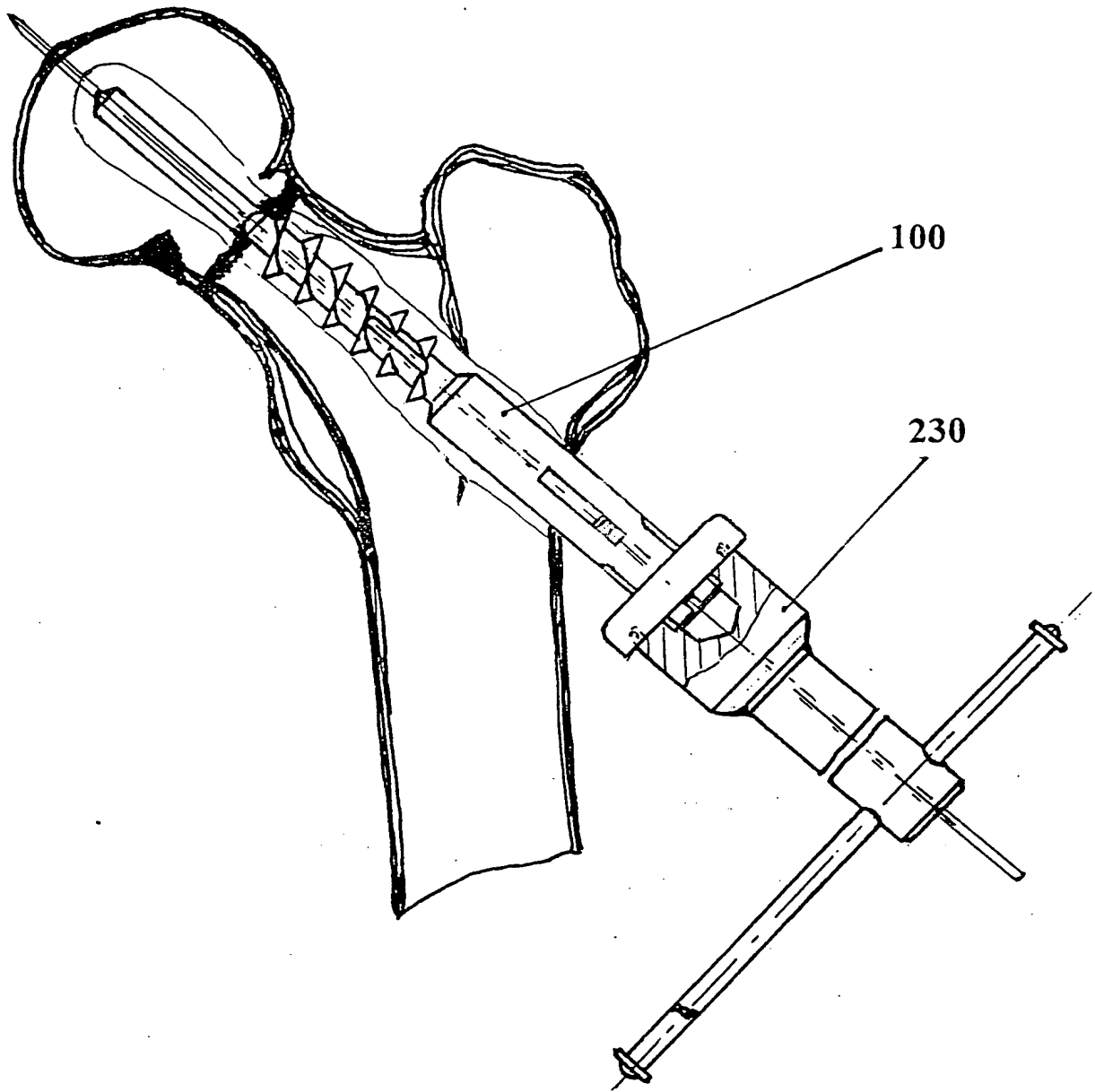


FIG. 20

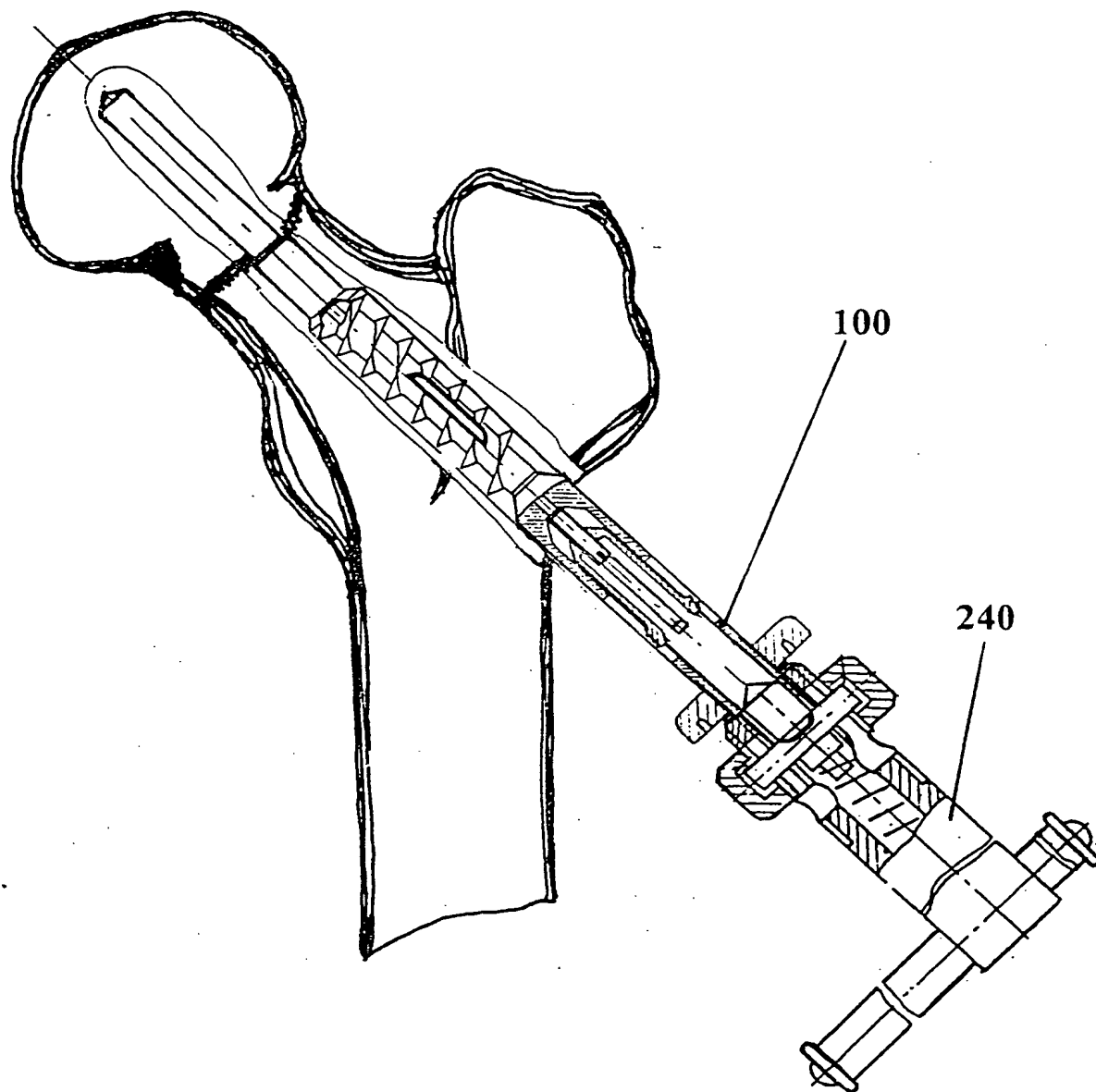


FIG. 21

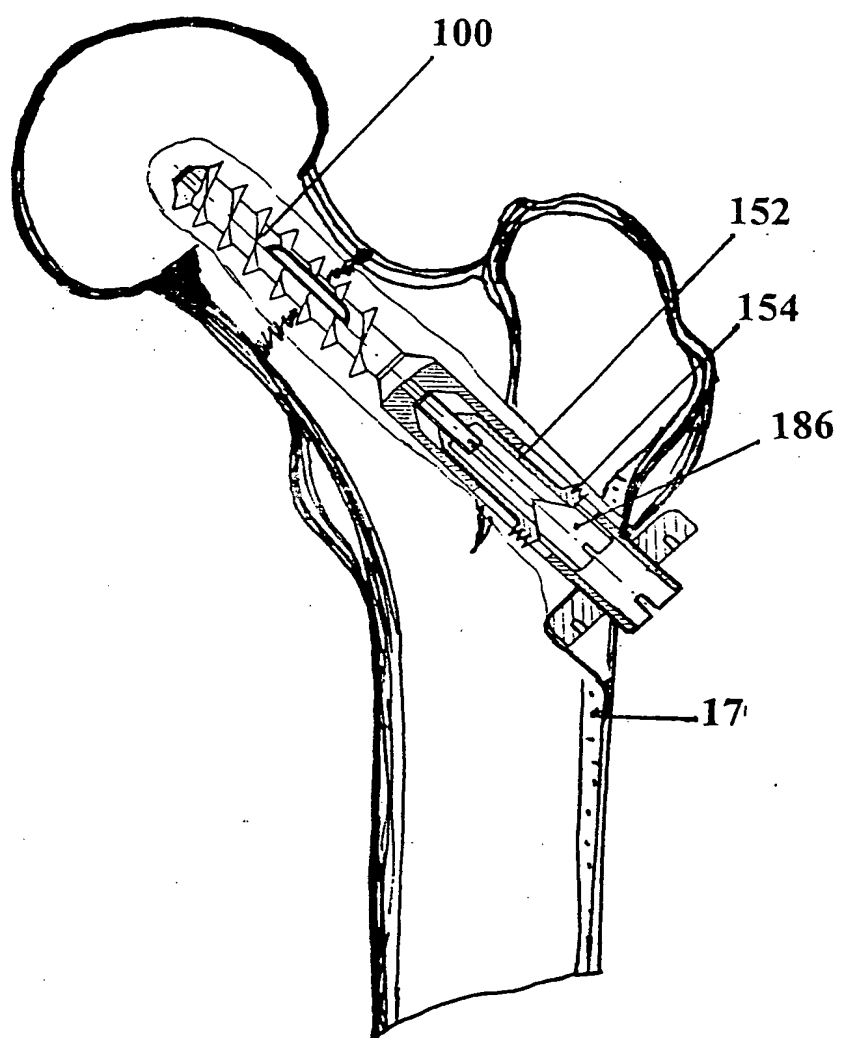


FIG. 22

**THIS PAGE BLANK (USPTO)**